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Price: EUR 3

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⁽¹⁾ Text with EEA relevance

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 413/2013

of 6 May 2013

concerning the authorisation of a preparation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for use in water for drinking for weaned piglets, pigs for fattening, laying hens and chickens for fattening (holder of authorisation Lallemand SAS)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for a new use of a preparation of *Pediococcus acidilactici* CNCM MA 18/5M. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns a request of a new use of a preparation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for use in water for drinking on weaned piglets, pigs for fattening, laying hens and chickens for fattening, to be classified in the additive category 'zootechnical additives'.
- (4) The use of that preparation of *Pediococcus acidilactici* CNCM MA 18/5M was authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 1200/2005⁽²⁾ and for pigs for fattening by Commission Regulation (EC) No 2036/2005⁽³⁾, for 10 years for salmonids and shrimps by Commission Regulation (EC) No 911/2009⁽⁴⁾, for weaned piglets by

Commission Regulation (EU) No 1120/2010⁽⁵⁾, for laying hens by Commission Regulation (EU) No 212/2011⁽⁶⁾ and for all fish other than salmonids by Commission Implementing Regulation (EU) No 95/2013⁽⁷⁾.

- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 June 2012⁽⁸⁾ that, under the proposed conditions of use, the preparation of *Pediococcus acidilactici* CNCM MA 18/5M, does not have an adverse effect on animal health, human health or the environment, and that it has the potential to improve the performance in target species.
- (6) The assessment of the preparation of *Pediococcus acidilactici* CNCM MA 18/5M shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 195, 27.7.2005, p. 6.

⁽³⁾ OJ L 328, 15.12.2005, p. 13.

⁽⁴⁾ OJ L 257, 30.9.2009, p. 10.

⁽⁵⁾ OJ L 317, 3.12.2010, p. 12.

⁽⁶⁾ OJ L 59, 4.3.2011, p. 1.

⁽⁷⁾ OJ L 33, 2.2.2013, p. 19.

⁽⁸⁾ EFSA Journal 2012; 10(7):2776.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 May 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/l of water for drinking			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4d1712	Lallemand SAS	<i>Pediococcus acidilactici</i> CNCM MA 18/5M	<i>Additive composition</i> Preparation of <i>Pediococcus acidilactici</i> CNCM MA 18/5M containing a minimum of 1×10^{10} CFU/g additive <i>Characterisation of active substance</i> Viable cells of <i>Pediococcus acidilactici</i> CNCM MA 18/5 M <i>Analytical methods</i> ⁽¹⁾ Enumeration: spread plate method using MRS agar (EN 15786:2009) Identification: Pulsed Field Gel Electrophoresis (PFGE)	Piglets (weaned) Pigs for fattening Laying hens Chickens for fattening	—	5×10^8	—	1. In the directions for use of the additive indicate the storage temperature, storage life. 2. For piglets (weaned) up to 35 kg. 3. For safety: breathing protection, glasses and gloves shall be used during handling. 4. The water for drinking containing the additive may be used simultaneously with feed for chickens for fattening containing the following coccidiostats: decoquinate, halofuginone, narasin, salinomycin sodium, maduramicin ammonium, diclazuril. 5. The additive shall be mixed with other feed additives or feed materials in order to allow its complete homogeneous dispersion in water for drinking	27 May 2023

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

COMMISSION IMPLEMENTING REGULATION (EU) No 414/2013**of 6 May 2013****specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 17(7) thereof,

Whereas:

- (1) Regulation (EU) No 528/2012 specifies procedures for applying for and granting authorisation of biocidal products.
- (2) Where applications are submitted to the same receiving competent authority or to the Agency for two or more authorisations of biocidal products with the same properties, the authorisations may be granted based on one single product evaluation and, as the case may be, comparative assessment. It is therefore appropriate to provide for an adapted authorisation procedure for such cases.
- (3) The terms and conditions relating to the making available on the market and use of a biocidal product should be based on the evaluation made of the product. It is therefore appropriate to require that biocidal products authorised in accordance with this Regulation are authorised on the same terms and conditions as the evaluated biocidal products to which they refer, with the exception of the details on which the products differ.
- (4) Since this Regulation specifies a procedure provided for by Regulation (EU) No 528/2012, which applies from 1 September 2013, this Regulation should also apply from that date.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

*Article 1***Subject matter**

This Regulation lays down the procedure applicable where an authorisation is sought for a product (the 'same product') which

is identical to another biocidal product or product family which has been authorised or registered in accordance with Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾ or Regulation (EU) No 528/2012, or for which an application for such registration or authorisation has been submitted (the 'related reference product'), with regards to all the latest information submitted in relation to the authorisation or registration, except information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council ⁽³⁾.

*Article 2***Content of applications**

By way of derogation from Article 20(1) of Regulation (EU) No 528/2012 and the information requirements in Article 43(1) thereof, an application for authorisation of a same product shall contain the following information:

- (a) the authorisation number or, for not yet approved related reference products, the application number in the Register for Biocidal Products of the related reference product;
- (b) an indication of the proposed differences between the same product and the related reference product, and evidence that the products are identical on all other aspects;
- (c) where required by Article 59(1) of Regulation (EU) No 528/2012, letters of access to all the data supporting the authorisation of the related reference product;
- (d) a draft summary of the biocidal product characteristics for the same product.

*Article 3***Submission and validation of applications for national authorisation**

1. Where the related reference product has been authorised by national authorisation or is the subject of an application for such an authorisation, applications for authorisation of a same product shall be submitted in accordance with Article 29(1) of Regulation (EU) No 528/2012 to the competent authority that has granted or is requested to grant the national authorisation of the related reference product.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ OJ L 123, 24.4.1998, p. 1.

⁽³⁾ OJ L 109, 19.4.2013, p. 4.

2. By way of derogation from paragraphs 2 and 4 of Article 29 of Regulation (EU) No 528/2012, the competent authority shall validate the application within 30 days of accepting it, provided that the information indicated in Article 2 has been submitted.

The validation shall include a check that the proposed differences between the same product and the related reference product concern merely information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013.

Article 4

Submission and validation of applications for Union authorisation

1. Where the related reference product has been authorised by Union authorisation or is the subject of an application for such an authorisation, applications for authorisation of a same product shall be submitted to the Agency in accordance with Article 43(1) of Regulation (EU) No 528/2012.

2. However, the application shall not include a confirmation that the biocidal product would have similar conditions of use across the Union or a reference to an evaluating competent authority.

3. For the purposes of the application of this Article, Article 43(2) of Regulation (EU) No 528/2012 shall be read as requiring the Agency to inform the applicant only.

4. By way of derogation from the first and second subparagraphs of Article 43(3) of Regulation (EU) No 528/2012, the Agency shall validate the application within 30 days of accepting it provided that the information indicated in Article 2 has been submitted.

5. The validation shall include a check that the proposed differences between the same product and the related reference product concern merely information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013.

6. For the purposes of the application of this Article, all references to the evaluating competent authority in the third subparagraph of Article 43(3) and in Article 43(4) and (5) of Regulation (EU) No 528/2012 shall be read as referring to the Agency.

Article 5

Evaluation and decision on applications for national authorisation

By way of derogation from Article 30 of Regulation (EU) No 528/2012, the receiving competent authority shall decide

whether to grant or refuse authorisation of a same product in accordance with Article 19 of that Regulation within 60 days from the validation of the application in accordance with Article 3, or, where applicable, from the subsequent date of adoption of the corresponding decision concerning the related reference product.

Article 6

Evaluation and decision on applications for Union authorisation

1. By way of derogation from Article 44(1), (2) and (3) of Regulation (EU) No 528/2012 the Agency shall prepare and submit to the Commission an opinion on the application within 30 days from the validation of the application in accordance with Article 4 of this Regulation, or, where applicable, on the subsequent date of submission of an opinion on the related reference product in accordance with Article 44(3) of Regulation (EU) No 528/2012.

2. If the Agency recommends the authorisation of the biocidal product, the opinion shall contain at least both the following elements:

- (a) a statement on whether the conditions laid down in Article 19 of Regulation (EU) No 528/2012 are fulfilled, and a draft summary of biocidal products characteristics, as referred to in Article 22(2) of that Regulation;
- (b) where relevant, details of any terms and conditions which should be imposed on the making available on the market and use of the biocidal product.

Article 7

Authorisations and changes of same products

1. A same product shall have a different authorisation number than that of the related reference product.

On all other aspects, the content of the authorisation of a same product shall be identical with that of the related reference product except in terms of the information in respect of which the products differ. The Register for Biocidal Products shall show a link between same products and related reference products.

2. Changes of a same product or of a related reference product shall be notified or applied for in accordance with Implementing Regulation (EU) No 354/2013 independently of each other.

Authorisations of a same product or of a related reference product may be changed or cancelled independently of each other.

However, in the evaluation of a proposed change of a same product or of a related reference product, the receiving competent authority or, where relevant, the Agency shall consider the appropriateness of cancelling or amending the authorisation of other products to which the product is linked in the Register for Biocidal Products as referred to in the second subparagraph of paragraph 1.

Article 8

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 September 2013.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 May 2013.

For the Commission

The President

José Manuel BARROSO

COMMISSION REGULATION (EU) No 415/2013**of 6 May 2013****laying down additional responsibilities and tasks for the EU reference laboratories for rabies, bovine tuberculosis and bee health, amending Regulation (EC) No 737/2008 and repealing Regulation (EU) No 87/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules⁽¹⁾, and in particular Article 32(6) thereof,

Whereas:

- (1) Regulation (EC) No 882/2004 lays down the general functions and duties for the EU reference laboratories for food and feed and for animal health set out in Annex VII thereto. In addition, Regulation (EC) No 882/2004 provides that the Commission may include in Annex VII thereto other EU reference laboratories relevant to the areas falling within the scope of that Regulation.
- (2) Regulation (EC) No 882/2004 also provides that, in addition to the general functions and duties of EU reference laboratories in the animal health sector laid down therein, additional responsibilities and tasks for those EU reference laboratories may be laid down by the Commission.
- (3) By Commission Regulation (EC) No 737/2008 of 28 July 2008 designating the Community reference laboratories for crustacean diseases, rabies and bovine tuberculosis, laying down additional responsibilities and tasks for the Community reference laboratories for rabies and bovine tuberculosis and amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council⁽²⁾, the Commission designated, inter alia, the EU reference laboratories for rabies and bovine tuberculosis and, consequently, inserted the relevant entries concerning those laboratories in Annex VII to Regulation (EC) No 882/2004. In addition, Annexes I and II to Regulation (EC) No 737/2008 set out certain specific responsibilities and tasks linked to the characteristics of the pathogens. Those responsibilities and tasks are additional to those laid down in Regulation (EC) No 882/2004.
- (4) By Commission Regulation (EU) No 87/2011 of 2 February 2011 designating the EU reference laboratory for bee health, laying down additional responsibilities and tasks for that laboratory and amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council⁽³⁾, the Commission designated the EU reference laboratory for bee health and, consequently, inserted the relevant entry concerning that laboratory in Annex VII to Regulation (EC) No 882/2004. In addition, the Annex to Regulation (EU) No 87/2011 sets out certain specific responsibilities and tasks linked to the characteristics of the agents liable to affect bee health. Those responsibilities and tasks are additional to those laid down in Regulation (EC) No 882/2004.
- (5) The definition of certain tasks of the EU reference laboratory for bee health in the Annex to Regulation (EU) No 87/2011 needs to be amended as regards serological tests because they are not applicable to testing on bees. As well the mention of colony collapse disorder (CCD) should be modified in order to ensure consistency with the terminology used in the surveillance studies on bee mortality established in Commission Implementing Decision 2012/362/EU⁽⁴⁾.
- (6) In the interest of clarity and simplification of Union legislation, it is appropriate that the provisions concerning those additional responsibilities and tasks of the EU reference laboratories for rabies, bovine tuberculosis and bee health be set out in only one act.
- (7) Regulation (EC) No 737/2008 should therefore be amended accordingly and Regulation (EU) No 87/2011 be repealed.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

In addition to the general functions and duties of EU reference laboratories in the animal health sector laid down in Article 32(2) of Regulation (EC) No 882/2004, the EU

⁽¹⁾ OJ L 165, 30.4.2004, p. 1.

⁽²⁾ OJ L 201, 30.7.2008, p. 29.

⁽³⁾ OJ L 29, 3.2.2011, p. 1.

⁽⁴⁾ OJ L 176, 6.7.2012, p. 65.

reference laboratory for rabies set out in point 16 of Part II of Annex VII to that Regulation shall also have the responsibilities and tasks set out in Annex I to this Regulation.

Article 2

In addition to the general functions and duties of EU reference laboratories in the animal health sector laid down in Article 32(2) of Regulation (EC) No 882/2004, the EU reference laboratory for bovine tuberculosis set out in point 17 of Part II of Annex VII to that Regulation shall also have the responsibilities and tasks set out in Annex II to this Regulation.

Article 3

In addition to the general functions and duties of EU reference laboratories in the animal health sector laid down in Article 32(2) of Regulation (EC) No 882/2004, the EU reference laboratory for bee health set out in point 18 of Part II of Annex VII to that Regulation shall also have the responsibilities and tasks set out in Annex III to this Regulation.

Article 4

Regulation (EC) No 737/2008 is amended as follows:

- (1) Articles 2 and 3 are deleted;
- (2) Annexes I and II are deleted.

Article 5

Regulation (EU) No 87/2011 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 6

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 May 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX I

Responsibilities and tasks of the EU reference laboratory for rabies, additional to those laid down in Article 32(2) of Regulation (EC) No 882/2004

1. The EU reference laboratory for rabies shall coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing rabies, in particular by:
 - (a) typing, storing and supplying strains of rabies virus;
 - (b) preparing, controlling and supplying international standard sera and other reference reagents to the national reference laboratories in order to standardise the tests and reagents used in the Member States;
 - (c) validating reference reagents including antigens and national standard sera submitted by the national reference laboratories;
 - (d) building up and maintaining a sera bank and a collection of rabies virus, and maintaining a database of strains isolated across the Union, including typing;
 - (e) organising periodical comparative tests of diagnostic procedures at Union level and operating laboratory proficiency tests of national reference laboratories;
 - (f) collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the Union;
 - (g) characterising rabies virus by the most up-to-date methods available to allow a greater understanding of the epidemiology of that disease;
 - (h) keeping abreast of developments in rabies surveillance, epidemiology and prevention throughout the world;
 - (i) acquiring a thorough knowledge of the preparation and use of the products of veterinary immunology used to eradicate and control rabies including the evaluation of vaccines.
2. The EU reference laboratory for rabies shall also:
 - (a) facilitate the harmonisation of techniques throughout the Union, in particular by specifying standard test methodologies;
 - (b) organise workshops for the benefit of national reference laboratories as agreed in the work programme and estimated budget referred to in Article 2 of Commission Implementing Regulation (EU) No 926/2011 ⁽¹⁾, including training of experts from the Member States and, as appropriate, from third countries, in new analytical methodologies;
 - (c) provide technical assistance to the Commission and, upon its request, participate in international forums relating to rabies, concerning in particular the standardisation of analytical diagnostic methods and their implementation.
3. In addition, the EU reference laboratory for rabies shall perform research activities and, whenever possible, coordinate research activities directed towards the improved control and eradication of rabies, in particular by:
 - (a) carrying out or collaborating with national reference laboratories in carrying out test validation trials;
 - (b) providing scientific advice to the Commission and collecting information and reports associated with the activities of the EU reference laboratory.

⁽¹⁾ OJ L 241, 17.9.2011, p. 2.

ANNEX II

Responsibilities and tasks of the EU reference laboratory for bovine tuberculosis, additional to those laid down in Article 32(2) of Regulation (EC) No 882/2004

1. The EU reference laboratory for bovine tuberculosis shall coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing bovine tuberculosis, in particular by:
 - (a) typing, storing and supplying strains of *Mycobacterium* sp. causing tuberculosis in animals;
 - (b) preparing, controlling and supplying reference reagents to the national reference laboratories in order to standardise the tests and reagents used in the Member States;
 - (c) validating reference reagents including antigens and tuberculins submitted by the national reference laboratories for bovine tuberculosis;
 - (d) building up and maintaining a collection of *Mycobacterium* sp. causing tuberculosis in animals, and maintaining a database of strains isolated across the Union including typing;
 - (e) organising periodical comparative tests of diagnostic procedures at Union level and operating laboratory proficiency tests of national reference laboratories;
 - (f) collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the Union;
 - (g) characterising *Mycobacterium* sp. causing tuberculosis in animals by the most up-to-date methods available to allow a greater understanding of the epidemiology of that disease;
 - (h) keeping abreast of developments in bovine tuberculosis surveillance, epidemiology and prevention throughout the world;
 - (i) acquiring a thorough knowledge of the preparation and use of the products of veterinary immunology used to eradicate and control bovine tuberculosis including the evaluation of vaccines.
 2. The EU reference laboratory for bovine tuberculosis shall also:
 - (a) facilitate the harmonisation of techniques throughout the Union, in particular by specifying standard test methodologies;
 - (b) organise workshops for the benefit of national reference laboratories as agreed in the work programme and estimated budget referred to in Article 2 of Implementing Regulation (EU) No 926/2011, including training of experts from the Member States and, as appropriate, from third countries, in new analytical methodologies;
 - (c) provide technical assistance to the Commission and, upon its request, to participate in international forums relating to the diagnostic of bovine tuberculosis, concerning in particular the standardisation of analytical diagnostic methods and their implementation.
 3. In addition, the EU reference laboratory for bovine tuberculosis shall perform research activities and, whenever possible, coordinate research activities directed towards the improved control and eradication of bovine tuberculosis, in particular by:
 - (a) carrying out or collaborating with national reference laboratories in carrying out test validation trials;
 - (b) providing scientific advice to the Commission and collecting information and reports associated with the activities of the EU reference laboratory.
-

ANNEX III

Responsibilities and tasks of the EU reference laboratory for bee health, additional to those laid down in Article 32(2) of Regulation (EC) No 882/2004

1. The EU reference laboratory for bee health shall coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing the relevant bee diseases, as necessary, in particular by:
 - (a) typing, storing and, where appropriate, supplying strains of the pathogenic agents to facilitate the diagnostic service in the Union;
 - (b) typing and antigenic and genomic characterisation of pathogenic agents, where relevant and necessary, for example for epidemiological follow-ups or verification of diagnosis;
 - (c) supplying standard sera and other reference reagents to the national reference laboratories in order to standardise the test and the reagents used in each Member State, where reference reagents are required;
 - (d) organising periodic comparative tests of diagnostic procedures at Union level with the national reference laboratories, in order to provide information on the methods of diagnosis used and the result of the tests carried out in the Union;
 - (e) retaining expertise on the *Tropilaelaps* mites and the small hive beetle (*Aethina tumida*) and other pertinent pathogenic agents to enable rapid differential diagnosis;
 - (f) determining the identity of the causative pathogenic agents, where necessary in close collaboration with regional reference laboratories designated by the World Organisation for Animal Health (OIE);
 - (g) building up and maintaining an up-to-date collection of pathogenic agents and their strains and an up-to-date collection of other reagents against bee disease pathogens when or if available;
 - (h) carrying out an inventory of the currently used techniques in the various laboratories;
 - (i) proposing standardised tests and test procedures or reference reagents for internal quality control;
 - (j) advising the Commission on scientific aspects related to bee health.
2. The EU reference laboratory for bee health shall also:
 - (a) assist actively in the diagnosis of outbreaks of the relevant disease in Member States by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies and communicating without delay the results of any investigations to the Commission, the Member States and the national reference laboratories concerned;
 - (b) facilitate the training or retraining of experts in laboratory diagnosis with a view to harmonising diagnostic techniques throughout the Union;
 - (c) organise workshops for the benefit of national reference laboratories as agreed in the work programme and estimated budget referred to in Article 2 of Regulation (EU) No 926/2011, including training of experts from the Member States and, as appropriate, from third countries, in new analytical methodologies;
 - (d) provide technical assistance to the Commission and, at its request, participate in international forums concerning, in particular, the standardisation of analytical methods and their implementation;
 - (e) develop monitoring activities and whenever possible coordinate activities directed towards an improvement of the bee health status in the Union, in particular by:
 - (i) carrying out or collaborating with national reference laboratories concerned in carrying out test validation trials;
 - (ii) providing scientific and technical support to the Commission and collecting information and reports associated with the activities of the EU reference laboratory;
 - (iii) establishing and coordinating a survey on honeybee colony losses in the Union with regard to establishing a baseline for 'normal' seasonal mortality of bees;
 - (f) collaborate with the relevant competent laboratories in third countries where those diseases are prevalent as regards methods of diagnosing bee diseases;
 - (g) collaborate with the relevant regional laboratories designated by the OIE with regard to exotic diseases (*Tropilaelaps* mites and the small hive beetle (*Aethina tumida*) and any other disease exotic to the Union);
 - (h) collate and forward information to the Commission and to national reference laboratories concerned on exotic and endemic diseases or pests that are potentially emerging and could affect the Union, including honeybee colony losses.

3. In addition, the EU reference laboratory for bee health shall:

- (a) perform experiments and field trials, in consultation with the Commission, directed towards an improved control of specific bee diseases;
 - (b) review at the annual meeting of national reference laboratories the relevant requirements for testing laid down in the OIE Terrestrial Animal Health Code and Manual of Diagnostic Tests and Vaccines for Terrestrial Animals;
 - (c) assist the Commission in reviewing the OIE's recommendations in the Terrestrial Animal Health Code and Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.
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COMMISSION IMPLEMENTING REGULATION (EU) No 416/2013**of 6 May 2013****entering a name in the register of traditional specialties guaranteed (Moules de bouchot (TSG))**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(2) thereof,

Whereas:

- (1) Regulation (EU) No 1151/2012 entered into force on 3 January 2013. It repealed and replaced Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialties guaranteed ⁽²⁾.
- (2) Pursuant to Article 8(2) of Regulation (EC) No 509/2006, France's application to register the name

'Moules de bouchot' was published in the *Official Journal of the European Union* ⁽³⁾.

- (3) As no statement of objection under Article 9 of Regulation (EC) No 509/2006 has been received by the Commission, that name should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name contained in the Annex to this Regulation is hereby entered in the register.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 May 2013.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ OJ L 93, 31.3.2006, p. 1.

⁽³⁾ OJ C 239, 9.8.2012, p. 13.

ANNEX

Agricultural products intended for human consumption listed in Annex I to the Treaty:

Class 1.7. Fresh fish, molluscs and crustaceans and products derived therefrom

FRANCE

Moules de bouchot (TSG)

COMMISSION IMPLEMENTING REGULATION (EU) No 417/2013**of 6 May 2013****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ⁽²⁾, and in particular Article 136(1) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multi-lateral trade negotiations, the criteria whereby the

Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

- (2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 May 2013.

*For the Commission,
On behalf of the President,*

*Jerzy PLEWA
Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	MA	69,1
	TN	103,2
	TR	125,9
	ZZ	99,4
0707 00 05	AL	65,0
	EG	158,2
	TR	128,4
	ZZ	117,2
0709 93 10	TR	132,1
	ZZ	132,1
0805 10 20	EG	54,8
	IL	71,5
	MA	59,4
	TN	67,7
	TR	72,9
	ZZ	65,3
0805 50 10	TR	80,9
	ZA	117,5
	ZZ	99,2
0808 10 80	AR	110,7
	BR	117,5
	CL	118,1
	CN	94,5
	MK	30,3
	NZ	135,8
	US	202,7
	ZA	114,4
	ZZ	115,5

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

GUIDELINES

GUIDELINE OF THE EUROPEAN CENTRAL BANK

of 22 March 2013

concerning statistics on holdings of securities

(ECB/2013/7)

(2013/215/EU)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular Articles 5.1, 12.1 and 14.3 thereof,

Having regard to Council Regulation (EC) No 2533/98 of 23 November 1998 concerning the collection of statistical information by the European Central Bank ⁽¹⁾,

Having regard to Regulation (EU) No 1011/2012 of the European Central Bank of 17 October 2012 concerning statistics on holdings of securities (ECB/2012/24) ⁽²⁾,

Whereas:

- (1) Regulation (EU) No 1011/2012 (ECB/2012/24) provides that reporting agents resident in a euro area Member State must report positions, transactions and, where available, other changes in the volume of securities they hold on a security-by-security basis. National central banks of the Member States whose currency is the euro (NCBs) are required to classify and aggregate these data. It is therefore necessary to define the procedures for NCBs to report to the European Central Bank (ECB), in compliance with Regulation (EU) No 1011/2012 (ECB/2012/24), statistical information derived from the data collected from the actual reporting population.
- (2) The Commission has published a proposal for a regulation of the European Parliament and of the Council on the European System of national and regional accounts in the European Union ⁽³⁾ (hereinafter 'ESA 2010'), which is an internationally compatible accounting framework used to describe the economies of the Member States, and which will replace ESA 95. The classification of data to be reported under this Guideline should follow the rules laid down in ESA 2010.

- (3) It is necessary to set up a procedure to carry out technical amendments to the Annexes to this Guideline in an effective manner, provided that such amendments neither change the underlying conceptual framework nor affect the reporting burden on reporting agents,

HAS ADOPTED THIS GUIDELINE:

Article 1

Scope

This Guideline establishes the obligations of the NCBs to report to the ECB statistics on holdings of securities collected pursuant to Regulation (EU) No 1011/2012 (ECB/2012/24).

Article 2

Definitions

The terms used in this Guideline have the same meaning as those defined in Regulation (EU) No 1011/2012 (ECB/2012/24).

Article 3

NCBs' reporting obligations for holdings of securities with an ISIN code

1. NCBs shall collect and report to the ECB statistical information on holdings of securities with an ISIN code, on a security-by-security basis, in accordance with the reporting schemes in Annex I, Part 1 (Tables 1 to 3) and Part 2 (Tables 1 to 3), and in compliance with electronic reporting standards which are laid down separately, for the following types of instruments: short-term debt securities (F.31); long-term debt securities (F.32); listed shares (F.511) and investment fund shares or units (F.52).

NCBs' reporting obligations shall cover end-of-quarter positions and either (i) end-of-quarter financial transactions over the reference quarter, or (ii) end-of-month or end-of-quarter data that are necessary to derive financial transactions, as laid down in paragraph 2.

⁽¹⁾ OJ L 318, 27.11.1998, p. 8.

⁽²⁾ OJ L 305, 1.11.2012, p. 6.

⁽³⁾ COM(2010) 774 final.

Financial transactions or data necessary to derive financial transactions that are reported by actual reporting agents to NCBs

in accordance with Part 1 of Annex I to Regulation (EU) No 1011/2012 (ECB/2012/24) shall be measured as laid down in Part 3 of Annex II to Regulation (EU) No 1011/2012 (ECB/2012/24).

2. NCBs shall report to the ECB the data mentioned in paragraph 1 for the following reference periods and in accordance with the following deadlines:

(a) with respect to holdings of securities by resident investors excluding NCBs, securities held in custody by resident custodians on behalf of investors resident in other euro area Member States and securities issued by euro area entities held in custody with resident custodians on behalf of non-euro area resident investors:

(i) NCBs shall report on a quarterly basis data on end-of-quarter security-by-security positions by close of business on the 70th calendar day following the end of the quarter to which the data relate;

(ii) NCBs shall report either (1) on a quarterly basis security-by-security transactions and, where available, other changes in volume over the reference quarter by close of business on the 70th calendar day following the end of the quarter to which the data relate; or (2) security-by-security positions and, where available, other changes in volume, which are necessary for the derivation of transactions. In this latter case, the NCBs shall report in accordance with the approaches described under Part 1 of Annex I to Regulation (EU) No 1011/2012 (ECB/2012/24) by close of business on the 70th calendar day following the end of the quarter to which the data relate for quarterly security-by-security data and on the 63rd calendar day following the end of the month to which the data relate for monthly security-by-security data;

(b) with respect to holdings of securities by reporting groups, including non-resident entities, NCBs shall report data on a quarterly basis on end-of-quarter security-by-security positions by the following deadlines:

(i) from 2013 to 2015, by close of business on the 70th calendar day following the end of the quarter to which the data relate; and

(ii) from 2016, by close of business on the 55th calendar day following the end of the quarter to which the data relate.

3. By September of every year, the ECB shall communicate to NCBs the exact transmission dates of data to be reported in the form of a reporting calendar for the following year.

4. The following general rules shall apply to the revision of monthly and quarterly data.

(a) NCBs shall report regular revisions as follows:

(i) revisions to monthly data with reference to the three months prior to the most recent quarter, which are transmitted on a quarterly basis, shall be sent together with the data for the most recent quarter (regular data transmission); revisions to monthly data with reference to the month prior to the most recent month, which are transmitted on a monthly basis, shall be sent together with the data for the most recent month (regular data transmission);

(ii) revisions to quarterly data with reference to the quarter prior to the most recent quarter shall be sent together with the data for the most recent quarter (regular data transmission);

(iii) revisions to the previous three years (12 quarters) shall be sent together with the regular transmission of data referring to the third quarter of the year;

(iv) the reporting of any other regular revisions not falling under points (i) to (iii) shall be agreed with the ECB;

(b) NCBs shall report exceptional revisions that significantly improve the quality of the data as soon as available and outside the regular transmission periods, subject to prior agreement with the ECB.

NCBs shall submit explanatory notes to the ECB setting out the reasons for significant revisions. NCBs may also submit explanatory notes for any other revisions on a voluntary basis.

5. The reporting requirements set out in this Article are subject to the following back data reporting requirements.

(a) NCBs shall, to the extent possible, report back data for the reference period starting from the first quarter of 2009 until the fourth quarter of 2013;

(b) where a Member State adopts the euro after this Guideline takes effect, the following rules shall apply:

(i) NCBs of Member States that joined the Union before December 2012 shall report back data to the ECB, on a best efforts basis, which cover at least (1) the data reference periods starting from March 2014, or (2) the five years preceding the adoption of the euro by the relevant Member State, whichever period is shorter;

(ii) NCBs of Member States that joined the Union after December 2012 shall report back data to the ECB, on a best efforts basis, which cover at least (1) the data reference periods starting from March 2016, or (2) the five years preceding the adoption of the euro by the relevant Member State, whichever period is shorter.

6. The accounting rules laid down in Article 5 of Regulation (EU) No 1011/2012 (ECB/2012/24) shall also apply when the NCBs report data in accordance with this Guideline.

Article 4

Reporting approaches for holdings of securities without an ISIN code

1. NCBs may decide whether to report to the ECB statistical information covering securities without an ISIN code held by MFIs, IFs, FVCs and heads of reporting groups subject to Regulation (EU) No 1011/2012 (ECB/2012/24) or held by custodians on behalf of (i) resident investors not subject to Regulation (EU) No 1011/2012 (ECB/2012/24), (ii) non-financial investors resident in other euro area Member States, or (iii) investors resident in non-euro area Member States, as defined in Regulation (EU) No 1011/2012 (ECB/2012/24), which are not granted a derogation from reporting requirements under Regulation (EU) No 1011/2012 (ECB/2012/24).

2. NCBs that report statistical information pursuant to paragraph 1 shall do so in accordance with the rules set out in Article 3(2), using the reporting schemes of Annex I, Part 1 (Tables 1, 2 and 4) and Part 2 (Tables 1, 2 and 4) as well as the electronic reporting standards laid down separately.

3. Quarterly data shall be revised in accordance with Article 3(4)(a) and (b).

4. NCBs shall submit explanatory notes to the ECB setting out the reasons for significant revisions. NCBs may also submit explanatory notes for any other revisions on a voluntary basis. In addition, NCBs shall provide information on significant reclassifications in the holder sectors or in the instrument classification, where available.

Article 5

Approaches for compiling statistics on holdings of securities held in custody

1. Notwithstanding the exemption from statistical reporting obligations that NCBs may grant to custodians in accordance with Article 4(5)(a) of Regulation (EU) No 1011/2012 (ECB/2012/24), to comply with Article 3, NCBs, after consulting the ECB, shall decide on the most appropriate approach for compiling statistics on securities held by investors not subject to reporting requirements under Regulation (EU) No 1011/2012 (ECB/2012/24), depending on the organisation of the relevant markets and the availability of other relevant statistical, public or supervisory information in the Member States.

2. If data on holdings of securities are not reported by custodians following the exemption granted in accordance with Article 4(5)(a) of Regulation (EU) No 1011/2012 (ECB/2012/24), and if NCBs obtain these data from other statistical or supervisory data sources, or if they collect them directly from investors in accordance with national arrangements, NCBs shall take all the following measures:

(a) ensure that these sources are sufficiently aligned with the statistical concepts and definitions laid down in Regulation (EU) No 1011/2012 (ECB/2012/24);

(b) monitor the quality of the data in accordance with the minimum statistical standards laid down in Annex III to Regulation (EU) No 1011/2012 (ECB/2012/24);

(c) if the reported data do not meet the quality standards referred to in subparagraph (b), increase the quality of such data, including the collection of data from custodians as provided for in Article 4(10) and (11) of Regulation (EU) No 1011/2012 (ECB/2012/24).

3. In addition, NCBs shall provide information on significant other changes in volume, where available, as defined in Part 3 of Annex II to Regulation (EU) No 1011/2012 (ECB/2012/24).

Article 6

Derogations

1. NCBs shall inform the ECB, at least once a year, of the derogations granted to, renewed or withdrawn from reporting agents for the following calendar year, as well as any ad hoc reporting requirements imposed on actual reporting agents that have been granted a derogation.

2. NCBs shall regularly check, at least once a year, the fulfilment of the conditions set out in Article 4 of Regulation (EU) No 1011/2012 (ECB/2012/24) for granting, renewing or withdrawing any derogation.

Article 7

Reference data on reporting groups' consolidated balance sheet assets

1. The ECB's Governing Council shall identify the reporting groups as set out, and according to the criteria laid down, in Article 2(4) of Regulation (EU) No 1011/2012 (ECB/2012/24) on the basis of end-of-December data corresponding to the preceding calendar year provided by NCBs to the ECB (hereinafter the 'reference data') for the purpose of deriving ESCB statistics on consolidated banking data for Member States.

2. By September of every year, the ECB shall communicate to NCBs the date in the following year by which NCBs are to transmit the reference data. Such transmission shall occur in time to allow the derivation of the total consolidated assets of European Union banks in July of every year.

Article 8

Notification procedure to heads of reporting groups

1. NCBs shall, on behalf of the ECB, use the template letter in Annex II (hereinafter the 'notification letter') to notify the heads of reporting groups of the Governing Council's decision pursuant to Article 2(4) of Regulation (EU) No 1011/2012 (ECB/2012/24) of their reporting obligations under the Regulation. The notification letter shall contain the criteria justifying the classification of the notified entity as head of a reporting group.

2. The relevant NCB shall send the notification letter to the head of a reporting group within 10 ECB working days following the date of the Governing Council's decision, and send a copy of that letter to the ECB Secretariat.

3. The procedure described in paragraph 2 shall not apply to the notification of heads of reporting groups, which have been identified by the Governing Council pursuant to Article 2(4) of Regulation (EU) No 1011/2012 (ECB/2012/24) prior to the date on which this Guideline takes effect.

Article 9

Review procedure by the Governing Council

1. If a head of a reporting group notified in accordance with Article 8 submits, within 15 ECB working days of the receipt of such notification, a reasoned written request with supporting information to the relevant NCB to review its classification as head of a reporting group, the relevant NCB shall transmit such request to the Governing Council within 10 ECB working days.

2. Following receipt of the written request pursuant to paragraph 1, the Governing Council shall review the classification and communicate its reasoned decision in writing, within two months of receipt of the request, to the relevant NCB, which shall notify the head of the reporting group of the Governing Council's decision within 10 ECB working days.

Article 10

Cooperation with competent authorities other than NCBs

1. Where all or part of the data described in Regulation (EU) No 1011/2012 (ECB/2012/24) can be obtained from competent authorities other than NCBs, NCBs shall establish appropriate cooperation mechanisms with these authorities to ensure a permanent structure for receiving such data.

2. NCBs shall ensure that the data referred to in paragraph 1 meet the ECB's minimum statistical standards set out in Annex III to Regulation (EU) No 1011/2012 (ECB/2012/24), as well as any other requirements set out in Regulation (EU) No 1011/2012 (ECB/2012/24), before transmitting them to the ECB in accordance with Article 3.

Article 11

Verification

1. Without prejudice to the ECB's verification rights set out in Regulations (EC) No 2533/98 and (EU) No 1011/2012 (ECB/2012/24), the NCBs shall monitor and ensure the quality and reliability of the statistical information made

available to the ECB and cooperate closely with the operators of the ESCB Securities Holdings Statistics Database (hereinafter the 'SHSDB') as part of overall data quality management.

2. The ECB shall assess these data in a similar manner, in close cooperation with the operators of the SHSDB. The assessment shall be carried out in a timely manner.

Article 12

Transmission standards

The NCBs shall use the ESCB-Net for the electronic transmission of the statistical information required by the ECB. The statistical information shall be made available to the ECB in accordance with electronic reporting standards laid down separately. Subject to the ECB's prior consent, other means may be used to transmit statistical information.

Article 13

Simplified amendment procedure

Taking account of the views of the ESCB Statistics Committee, the ECB's Executive Board may make technical amendments to the annexes to this Guideline, provided that such amendments neither change the underlying conceptual framework nor affect the reporting burden on reporting agents. The Executive Board shall inform the Governing Council of any such amendment without undue delay.

Article 14

Taking effect and implementation

This Guideline shall take effect on the day of its notification to the NCBs. The Eurosystem central banks shall comply with Articles 8 and 9 from the date of notification of the Guideline to the NCBs and with the remaining provisions of the Guideline from 1 January 2014.

Article 15

Addressees

This Guideline is addressed to all Eurosystem central banks.

Done at Frankfurt am Main, 22 March 2013.

For the Governing Council of the ECB
The President of the ECB
Mario DRAGHI

ANNEX I

REPORTING SCHEMES

PART 1

Holdings of securities by sector excluding holdings by national central banks

Table 1

General information and explanatory notes

Reported information ⁽¹⁾	Attribute	Status ⁽²⁾	Description
1. General information	Reporting institution	M	Identification code of the reporting institution
	Submission date	M	Date on which the data are submitted to the SHSDB
	Reference period	M	Period to which the data refer
	Reporting frequency	M	Quarterly data
			Monthly data ⁽³⁾
2. Explanatory notes (metadata)	M	Treatment of early redemptions	
	M	Treatment of accrued interest	

⁽¹⁾ The electronic reporting standards are laid down separately.

⁽²⁾ M: mandatory attribute; V: voluntary attribute.

⁽³⁾ Only for positions, if transactions are derived from monthly positions in the SHSDB.

Table 2

Information on holdings of securities

Reported information ⁽¹⁾	Attribute	Status ⁽²⁾	Description
Securities related information	Holder sector	M	Sector/subsector of the investor.
			Non-financial corporations (S.11) ⁽³⁾
			Deposit-taking corporations except central banks (S.122)
			Money market funds (MMF) (S.123)
			Non-MMF investment funds (S.124)
			Other financial corporations ⁽⁴⁾ excluding financial vehicle corporations
			Financial vehicle corporations
			Insurance corporations (S.128)
			Pension funds (S.129)

Reported information ⁽¹⁾	Attribute	Status ⁽²⁾	Description
			Insurance corporations and pension funds (subsector not identified) (S.128 + S.129) (transitional period)
			Central government (S.1311) (voluntary breakdown)
			State government (S.1312) (voluntary breakdown)
			Local government (S.1313) (voluntary breakdown)
			Social security funds (S.1314) (voluntary breakdown)
			Other general government (subsector not identified)
			Households excluding non-profit institutions serving households (S.14) (voluntary breakdown for resident investors, mandatory for third party holdings)
			Non-profit institutions serving households (S.15) (voluntary breakdown)
			Other households and non-profit institutions serving households (S.14 + S.15) (subsector not identified)
			Non-financial investors excluding households (only for third party holdings) (S.11 + S.13 + S.15) ⁽⁵⁾
			Central banks and general government to be reported only for holdings by non-euro area countries (S.121 + S.13) ⁽⁶⁾
			Investors other than central banks and governments to be reported only for holdings by non-euro area countries ⁽⁶⁾
			Unknown sector ⁽⁷⁾
Holder country	M		Country of residence of the investor
Source	M		Source of the submitted information on securities holdings
			Direct reporting
			Custodian reporting
			Mixed reporting ⁽⁸⁾

Reported information ⁽¹⁾	Attribute	Status ⁽²⁾	Description	
				Not available
Function	M		Function of the investment according to the classification of balance of payments statistics	
				Direct investment
				Portfolio investment
				Not specified
Reporting basis	M/V ⁽⁹⁾		Indicates how the security is quoted, as a percentage or in units	
				Percentage
				Units
Nominal currency	V		Currency in which the ISIN is denominated, reported when the reporting basis equals percentage	
Positions	M		Total amount of securities held	
				At nominal value ⁽¹⁰⁾ . Number of shares or units of a security or aggregated nominal amount (in nominal currency or euro) if the security is traded in amounts rather than in units, excluding the accrued interest
				At market value. Amount held at the price quoted in the market in euro, including accrued interest ⁽¹¹⁾
Positions: of which amount	M ⁽¹²⁾		Amount of securities held by the two largest investors	
				At nominal value, according to the same valuation method as positions
				At market value, according to the same valuation method as positions
Format	M ⁽¹⁰⁾		Specifies the format used for the positions at nominal value	
				Nominal value in euro or other relevant currency
				Number of shares/units ⁽¹³⁾
Other changes in volume	M		Other changes in the amount of the security held	

Reported information ⁽¹⁾	Attribute	Status ⁽²⁾	Description	
				At nominal value in the same format as the positions at nominal value
				At market value in euro
	Other changes in volume: of which amount	M ⁽¹²⁾	Other changes in volume in the amount held by the two largest investors	
				At nominal value, according to the same valuation method as positions
				At market value, according to the same valuation method as positions
Financial transactions		M ⁽¹⁴⁾	Sum of purchases minus sales of a security, recorded at transaction value in euro including accrued interest ⁽¹⁵⁾	
Financial transactions: of which amount		M ⁽¹²⁾ , ⁽¹⁶⁾	Sum of the two largest transactions in absolute terms by individual holders, according to the same valuation method as the financial transactions	
Confidentiality status		M ⁽¹⁷⁾	Confidentiality status for positions, transactions, other changes in volume	
				Not for publication, restricted for internal use only
				Confidential statistical information
				Not applicable ⁽¹⁸⁾

⁽¹⁾ The electronic reporting standards are laid down separately.

⁽²⁾ M: mandatory attribute; V: voluntary attribute.

⁽³⁾ The numbering of categories throughout this Guideline reflects the numbering introduced in ESA 2010.

⁽⁴⁾ Other financial intermediaries (S.125) plus financial auxiliaries (S.126) plus captive financial institutions and money lenders (S.127).

⁽⁵⁾ Only if sectors S.11, S.13 and S.15 are not reported separately.

⁽⁶⁾ For data reported by non-euro area national central banks, only for reporting holdings by non-resident investors.

⁽⁷⁾ Unallocated sector resident in the holder country; i.e. unknown sectors of unknown countries should not be reported. NCBs shall inform SHSDB operators of the reason for the unknown sector, in case of statistically relevant values.

⁽⁸⁾ Only if direct and custodian reporting cannot be distinguished.

⁽⁹⁾ Mandatory for reporting securities with an ISIN code; voluntary for reporting securities without an ISIN code.

⁽¹⁰⁾ Not reported if market values (and the respective other changes in volume/transactions) are reported.

⁽¹¹⁾ The inclusion of accrued interest is recommended, on a best efforts basis.

⁽¹²⁾ If an NCB reports the confidentiality status, this attribute may not be reported. The amount may refer to the largest single investor, instead of the two largest investors, under the responsibility of the reporting NCB.

⁽¹³⁾ NCBs are encouraged to report nominal value in number of units when securities are quoted in units in the CSDB.

⁽¹⁴⁾ To be reported only if transactions are not derived from positions in the SHSDB.

⁽¹⁵⁾ The inclusion of accrued interest is recommended, on a best efforts basis.

⁽¹⁶⁾ To be reported only for transactions collected from reporting agents, not reported for transactions derived from positions by NCBs.

⁽¹⁷⁾ To be reported if the corresponding amount of the two largest investors for positions, transactions, other changes in volume, respectively, is not available/provided.

⁽¹⁸⁾ To be used only if transactions are derived from positions by NCBs. In these cases the confidentiality status will be derived by the SHSDB, i.e. if the initial and/or final positions are confidential, the derived transaction is flagged as confidential.

Table 3

Holdings of securities with an ISIN code

Reported information ⁽¹⁾	Attribute	Status ⁽²⁾	Description
Reference data	ISIN code	M	ISIN code

⁽¹⁾ The electronic reporting standards are laid down separately.

⁽²⁾ M: mandatory attribute; V: voluntary attribute.

Table 4

Holdings of securities without an ISIN code

Reported information ⁽¹⁾	Attribute	Status ⁽²⁾	Description
1. Basic reference data	Aggregation flag	M	Type of data
			Data reported on a security-by-security basis
			Aggregated data (no security-by-security)
	Securities/aggregates identification number	M	Internal securities identification number for securities without an ISIN code and aggregated data on securities holdings
	Securities identification number type	M ⁽³⁾	Specifies the securities identification number for securities reported on a security-by-security basis ⁽⁴⁾
			NCB internal number
			CUSIP
			SEDOL
			other (to be specified in metadata)
	Instrument classification	M	Classification of the security according to ESA 2010 and Regulation (EU) No 1011/2012 (ECB/2012/24)
			Short-term debt securities (F.31)
			Long-term debt securities (F.32)
			Listed shares (F.511)
			Investment fund shares or units (F.52)
			Other security types ⁽⁵⁾
	Issuer sector	M	Institutional sector of the issuer according to ESA 2010 and Regulation (EU) No 1011/2012 (ECB/2012/24)
	Issuer country	M	Country of legal incorporation or domicile of the issuer of the security

Reported information ⁽¹⁾	Attribute	Status ⁽²⁾	Description
	Price value ⁽⁶⁾	V	Price of the security at the end of the reference period
	Price value basis ⁽⁶⁾	V	Basis on which the price value is given
			euro or other relevant currency
			Percentage
2. Additional reference data	Issuer name	V	Name of the issuer
	Short name	V	Short name of the security given by issuer, defined according to the characteristics of the security and any other available information
	Issue date	V	The date on which the securities are delivered to the underwriter by the issuer against payment. This is the date when the securities are available for delivery to investors for the first time
	Maturity date	V	Date on which the instrument is redeemed
	Amount outstanding	V	Amount outstanding converted into euro
	Market capitalisation	V	Latest available market capitalisation in euro
	Accrued interest	V	Interest accrued since the last coupon payments or the accrual start date
	Last split factor	V	Stock splits and reverse splits of shares
	Last split date	V	Date from which the stock split becomes effective
	Coupon type	V	Type of coupon (fixed, floating, stepped, etc.)
	Debt type	V	Type of debt instrument
	Dividend amount	V	Amount of last dividend payment per share in dividend amount type before tax (gross dividend)
	Dividend amount type	V	Denomination either in dividend currency or number of shares
	Dividend currency	V	Currency of last dividend payment
	Asset securitisation type	V	Type of securing asset

⁽¹⁾ The electronic reporting standards are laid down separately.

⁽²⁾ M: mandatory attribute; V: voluntary attribute.

⁽³⁾ Not required for securities reported on an aggregated basis.

⁽⁴⁾ NCBs should preferably use the same securities identification number for each security over several years. In addition, each securities identification number should be related to only one security. NCBs must inform the SHSDB operators if they are not in a position to do so. CUSIP and SEDOL codes may be treated as NCB internal numbers.

⁽⁵⁾ These securities will not be included in the production of aggregates.

⁽⁶⁾ To calculate positions at market value from positions at nominal value.

PART 2

Holdings of securities by reporting groups

Table 1

General information and explanatory notes

Reported information ⁽¹⁾	Attribute		Status ⁽²⁾	Description
1. General information	Reporting institution		M	Identification code of the reporting institution
	Submission date		M	Date on which the data are submitted to the SHSDB
	Reference period		M	Period to which the data refer
	Reporting frequency		M	Quarterly data
2. Explanatory notes (metadata)	M	Treatment of early redemptions		
	M	Treatment of accrued interest		

⁽¹⁾ The electronic reporting standards are laid down separately.

⁽²⁾ M: mandatory attribute; V: voluntary attribute.

Table 2

Information on holdings of securities

Reported information ⁽¹⁾	Attribute		Status ⁽²⁾	Description
Securities related information	Reporting group ID		M	ID of the reporting group ⁽³⁾
	Residency of the entities of the group		V	Residency of the entities of the group, when reported separately from head office ⁽⁴⁾
				Resident in the country of the head office
				Not resident in the country of the head office
				If not resident in the country of the head office, resident of other euro area countries
				If not resident in the country of the head office, resident outside the euro area
	Entity ID		V	ID of the entity of the group ⁽³⁾
	Country of residency of the entity		V	Country of legal incorporation or domicile of the entity
	Group type		M	Group type
				Banking group
	Reporting basis		M	Indicates how the security is quoted, as a percentage or in units

Reported information ⁽¹⁾	Attribute	Status ⁽²⁾	Description	
				Percentage
				Units
	Nominal currency	V	Currency in which the ISIN is denominated, reported when reporting basis equals percentage	
	Format	M ⁽⁵⁾	Specifies the format used for the positions at nominal value	
				Nominal value in euro or other relevant currency
				Number of shares/units ⁽⁶⁾
	Positions	M	Total amount of securities held	
				At nominal value ⁽⁵⁾ . Number of shares or units of a security or aggregated nominal amount in nominal currency or euro if the security is traded in amounts rather than in units, excluding the accrued interest
				At market value. Amount held of a security at the price quoted in the market in euro, including accrued interest ⁽⁷⁾
	Other changes in volume	V	Other changes in volume in the amount of the security held	
				At nominal value in the same format as the positions at nominal value ⁽⁵⁾
				At market value in euro
	Financial transactions	V	Sum of purchases minus sales of a security, recorded at transaction value in euro including accrued interest ⁽⁷⁾	
	Issuer is part of the reporting group	V	Indicates whether the security was issued by an entity of the same reporting group	

⁽¹⁾ The electronic reporting standards are laid down separately.

⁽²⁾ M: mandatory attribute; V: voluntary attribute.

⁽³⁾ Identifier to be defined separately.

⁽⁴⁾ NCBs may report according to four alternative options: (1) aggregated for all entities of the group including the head office; (2) aggregated for entities resident in the country of the head office; and aggregated for entities non-resident in the country of the head office, respectively; (3) aggregated for entities resident in the country of the head office; aggregated for entities resident in another euro area country; aggregated for entities resident outside the euro area; (4) entity by entity.

⁽⁵⁾ Not reported if market values are reported.

⁽⁶⁾ NCBs are encouraged to report nominal value in number of units when securities are quoted in units in the CSDB.

⁽⁷⁾ The inclusion of accrued interest is recommended, on a best efforts basis.

Table 3

Holdings of securities with an ISIN code

Reported information ⁽¹⁾	Attribute	Status ⁽²⁾	Description
Reference data	ISIN code	M	ISIN code

⁽¹⁾ The electronic reporting standards are laid down separately.

⁽²⁾ M: mandatory attribute; V: voluntary attribute.

Table 4

Holdings of securities without an ISIN code

Reported information ⁽¹⁾	Attribute	Status ⁽²⁾	Description
1. Basic reference data	Aggregation flag	M	Type of data
			Data reported on a security-by-security basis
			Aggregated data (no security-by-security)
	Securities identification number	M	Internal NCB identification number for holdings of securities without an ISIN code reported on a security-by-security basis, or on an aggregated basis
	Securities identification number type	M ⁽³⁾	Specifies the securities identification number for securities reported on a security-by-security basis ⁽⁴⁾
			NCB internal number
			CUSIP
			SEDOL
			Other ⁽⁵⁾
	Instrument classification	M	Classification of the security according to ESA 2010 and Regulation (EU) No 1011/2012 (ECB/2012/24)
			Short-term debt securities
			Long-term debt securities
			Quoted shares
			Investment fund shares
			Other security types ⁽⁶⁾
	Issuer sector	M	Institutional sector of the issuer according to ESA 2010 and Regulation (EU) No 1011/2012 (ECB/2012/24)

Reported information ⁽¹⁾	Attribute	Status ⁽²⁾	Description
	Issuer country	M	Country of legal incorporation or domicile of the issuer of the security
	Price value ⁽⁷⁾	V	Price of the security at the end of the reference period
	Price value basis ⁽⁷⁾	V	Specifies the basis on which the price value is given
			euro or other relevant currency
			Percentage
2. Additional reference data	Issuer name	V	Name of the issuer
	Short name	V	Short name of the security given by issuer, defined according to the characteristics of the issue and any other available information
	Issuer is part of the reporting group	V	Indicates whether the security was issued by an entity of the same reporting group for securities reported on a security-by-security basis
	Issue date	V	The date on which the securities are delivered to the underwriter by the issuer against payment. This is the date when the securities are available for delivery to investors for the first time
	Maturity date	V	Date on which the debt instrument is redeemed
	Amount outstanding	V	Amount outstanding converted into euro
	Market capitalisation	V	Latest available market capitalisation in euro
	Accrued interest	V	Interest accrued since the last coupon payments or the accrual start date
	Last split factor	V	Stock splits and reverse splits of shares
	Last split date	V	Date from which the stock split becomes effective
	Coupon type	V	Type of coupon (fixed, floating, stepped, etc.)
	Debt type	V	Type of debt instrument
	Dividend amount	V	Amount of last dividend payment per share in dividend amount type before tax (gross dividend)

Reported information ⁽¹⁾	Attribute	Status ⁽²⁾	Description
	Dividend amount type	V	Denomination either in dividend currency or number of shares
	Dividend currency	V	Currency of last dividend payment
	Asset securitisation type	V	Type of securing asset

⁽¹⁾ The electronic reporting standards are laid down separately.

⁽²⁾ M: mandatory attribute; V: voluntary attribute.

⁽³⁾ Not required for securities reported on an aggregated basis.

⁽⁴⁾ NCBs should preferably use the same securities identification number for each security over several years. In addition, each securities identification number should be related to only one security. NCBs must inform the SHSDB operators if they are not in a position to do so. CUSIP and SEDOL codes may be treated as NCB internal numbers.

⁽⁵⁾ NCBs should specify in the metadata the type of identification number used.

⁽⁶⁾ These securities will not be included in the production of aggregates.

⁽⁷⁾ To calculate positions at market value from positions at nominal value.

ANNEX II

LETTER OF NOTIFICATION TO HEADS OF REPORTING GROUPS

Notification of classification as head of reporting group pursuant to Regulation (EU) No 1011/2012 of the European Central Bank of 17 October 2012 concerning statistics on holdings of securities (ECB/2012/24) ⁽¹⁾

[Dear Sir/Madam]

We hereby notify you, on behalf of the European Central Bank (ECB), that [legal name of head of reporting group] has been classified by the ECB's Governing Council as head of a reporting group for statistical purposes, in accordance with Articles 1(11) and 2(4) of Regulation (EU) No 1011/2012 (ECB/2012/24).

The reporting obligations of [legal name of head of the reporting group] as head of a reporting group are laid down in Article 3(3) of Regulation (EU) No 1011/2012 (ECB/2012/24).

Reasons for classification as 'head of a reporting group'

The Governing Council has determined that [legal name of head of the reporting group] qualifies as head of a reporting group according to the following criteria, under Regulation (EU) No 1011/2012 (ECB/2012/24):

(a) [legal name of head of the reporting group] is head of a banking group, as defined in Article 1(10) of Regulation (EU) No 1011/2012 (ECB/2012/24);

(b) the banking group that [legal name of head of the reporting group] is heading meets the following criteria ⁽²⁾:

(i) [the consolidated balance sheet assets of the banking group, calculated pursuant to Section 1 of Chapter 4 of Title V of Directive 2006/48/EC of the European Parliament and of the Council of 14 June 2006 relating to the taking up and pursuit of the business of credit institutions ⁽³⁾, is larger than 0,5 % of the total consolidated balance sheet assets of the European Union banking groups, according to the most recent data available to the ECB, i.e. (a) data with reference to the end of December of the calendar year preceding the sending of this notification letter; or (b) if the data under (a) are not available, data with reference to the end of December of the year before];

(ii) [the banking group is important for the stability and the functioning of the financial system in the euro area for the following reason: [add here the justification that makes the banking group important for the stability and the functioning of the financial system in the euro area:

— the banking group is closely and extensively interconnected with other financial institutions in the euro area;

— the banking group has a strong and extensive cross-border activity;

— the banking group activity is largely concentrated in one segment of the euro area banking business, for which it represents a major player;

— the banking group has a complex corporate structure which goes beyond the domestic territory];

(iii) [the banking group is important for the stability and the functioning of the financial system in [relevant euro area Member States] for the following reason: [add here the justification that makes the banking group important for the stability and the functioning of the financial system in the relevant euro area Member States:

— the banking group is closely and extensively interconnected with other financial institutions in the domestic territory;

— the banking group activity is largely concentrated in [specify the segment of banking business], in which it is a major domestic player]].

⁽¹⁾ OJ L 305, 1.11.2012, p. 6.

⁽²⁾ Insert the relevant criteria that the notified entity meets to qualify as head of a reporting group, as decided by the Governing Council.

⁽³⁾ OJ L 177, 30.6.2006, p. 1.

Information source supporting the classification as 'head of a reporting group'

The ECB derives the total consolidated balance sheet assets of the European Union banking groups on the basis of information collected from national central banks on the consolidated balance sheet of banking groups in the relevant Member State, calculated pursuant to Section 1 of Chapter 4 of Title V of Directive 2006/48/EC.

[Where necessary, further explanations of the methodology applied to any additional inclusion criteria agreed by the Governing Council should be incorporated here.]

Objections and Governing Council review

Any request for review by the ECB's Governing Council of the classification of *[legal name of head of the reporting group]* as head of a reporting group as a result of the justifications given above is to be addressed within 15 ECB working days of receipt of this letter to *[insert NCB's name and address]*. *[legal name of head of the reporting group]* shall include the reasons for such a request and all supporting information.

Starting date of the reporting obligations

In the absence of any objection, *[legal name of head of the reporting group]* is to report statistical information pursuant to Article 3(3) of Regulation (EU) No 1011/2012 (ECB/2012/24) by *[insert starting date for reporting, i.e. no later than six months after sending the letter]*.

Changes to the status of the notified entity

You are requested to inform *[name of notifying NCB]* of any change of *[legal name of head of the reporting group]*'s name or legal form, merger, restructuring and any other event or circumstances that may affect *[legal name of head of the reporting group]*'s reporting obligations, within 10 ECB working days of such event.

Notwithstanding the occurrence of such event, *[legal name of head of the reporting group]* will remain subject to the reporting obligations set out in Regulation (EU) No 1011/2012 (ECB/2012/24) until we notify you otherwise on behalf of the ECB.

Yours faithfully

[signature]

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

RECOMMENDATION OF THE EU-PALESTINIAN AUTHORITY JOINT COMMITTEE

of 14 April 2013

on the implementation of the European Union-Palestinian Authority European Neighbourhood Policy Action Plan

THE EU-PALESTINIAN AUTHORITY JOINT COMMITTEE,

Having regard to the euro-Mediterranean Interim Association Agreement on trade and cooperation between the European Community, of the one part, and the Palestine Liberation Organisation (PLO) for the benefit of the Palestinian Authority of the West Bank and the Gaza Strip, of the other part ⁽¹⁾, and in particular Article 63(2) thereof,

Whereas:

(1) Pursuant to Article 70 of euro-Mediterranean Interim Association Agreement on trade and cooperation between the European Community, of the one part, and the Palestine Liberation Organisation (PLO) for the benefit of the Palestinian Authority of the West Bank and the Gaza Strip, of the other part ('the Agreement'), the Parties shall take any general or specific measures required to fulfil their obligations under the Agreement and shall see to it that the objectives set out in the Agreement are attained.

(2) The Parties to the Agreement have agreed on the text of the European Union – Palestinian Authority European Neighbourhood Policy Action Plan ('the EU-PA ENP Action Plan').

(3) The EU-PA ENP Action Plan should support the implementation of the Agreement through the drawing up and adoption of concrete steps with a view to attaining its objectives.

(4) The EU-PA ENP Action Plan serves the dual purpose of setting out concrete steps with a view to the respect, by the parties, of the obligations set out in the Agreement and of providing a broader framework for further strengthening EU-PA relations.

HEREBY RECOMMENDS that the Parties implement the EU-PA ENP Action Plan ⁽²⁾ insofar as such implementation is directed towards attainment of the objectives of the euro-Mediterranean Interim Association Agreement on trade and cooperation between the European Community, of the one part, and the Palestine Liberation Organisation (PLO) for the benefit of the Palestinian Authority of the West Bank and the Gaza Strip, of the other part,

Done at Brussels, 14 April 2013.

*For the EU-Palestinian
Authority Joint Committee*
The President
C. ASHTON

⁽¹⁾ OJ L 187, 16.7.1997, p. 3.

⁽²⁾ <http://register.consilium.europa.eu/pdf/en/12/st17/st17814.en12.pdf>

CORRIGENDA

Corrigendum to Commission Decision 2012/481/EU of 16 August 2012 establishing the ecological criteria for the award of the EU Ecolabel for printed paper*(Official Journal of the European Union L 223 of 21 August 2012)*

On page 58, Subcriterion 2(a), List of hazard statements and risk phrases:

<i>for:</i>	H330 Fatal if inhaled	R26'
<i>read:</i>	H330 Fatal if inhaled	R23 or R26'

on page 62, Criterion 3:

for: 'Assessment and verification: the applicant shall provide the test result of the recyclability for wet strength agents and removability for adhesives. The reference test methods are PTS method PTS-RH 021/97 (for wet strength agents), INGEDE Method 12 (for non-soluble adhesive removability), or equivalent test methods. The deinkability shall be proven by using the "Deinking Scorecard" ⁽¹⁾ of the European Recovered Paper Council or equivalent test methods. Testing must be performed on three types of paper: uncoated, coated and surface-sized paper. If a type of printing ink is only sold for one or two specific types of paper, it is sufficient to test the paper type(s) in question. The applicant shall provide a declaration that coated and laminated printed paper products are in compliance with point 3(b). Where a part of a printed paper product is easily removable (for instance a plastic cover or a reusable exercise book cover), the recyclability test may be made without this component. The easiness of removal of the non-paper components shall be proven via a declaration of the paper collecting company, the recycling company or an equivalent organisation. Test methods shown by a competent and independent third party as giving equivalent results may also be used.'

read: 'Assessment and verification: the applicant shall provide the test result of the recyclability for wet strength agents and removability for adhesives. The reference test methods are PTS method PTS-RH 021/97 (for wet strength agents), INGEDE Method 12 (for non-soluble adhesive removability) or equivalent test methods. The deinkability shall be proven by using the "Deinking Scorecard" ⁽¹⁾ of the European Recovered Paper Council or equivalent test methods. Testing must be performed on three types of paper: uncoated, coated and surface-sized paper. If a type of printing ink is only sold for one or two specific types of paper, it is sufficient to test the paper type(s) in question. The applicant shall provide a declaration that coated and laminated printed paper products are in compliance with point 3(c). Where a part of a printed paper product is easily removable (for instance a plastic cover or a reusable exercise book cover), the recyclability test may be made without this component. The easiness of removal of the non-paper components shall be proven via a declaration of the paper collecting company, the recycling company or an equivalent organisation. Test methods shown by a competent and independent third party as giving equivalent results may also be used.'

on page 64, Subcriterion 5(b):

for: '(b) Waste paper

The amount of waste paper "X" produced shall be:

Printing method	Maximum Waste paper (%)
Sheet offset	23
Coldset, newspaper	10
Coldset, form printing	18
Coldset rotation (except newspapers and forms)	19
Heatset rotation	21
Gravure printing	15
Flexography (except corrugated fibreboard)	11

Printing method	Maximum Waste paper (%)
Digital printing	10
Offset	4
Flexography, corrugated fibreboard	17
Screen printing	23'

read: '(b) Waste paper

The amount of waste paper "X" produced shall be:

Printing method	Maximum Waste paper (%)
Sheet offset	23
Coldset, newspaper	10
Coldset, form printing	18
Coldset rotation (except newspapers and forms)	19
Heatset rotation	21
Gravure printing	15
Flexography (except corrugated fibreboard)	11
Digital printing	10
Flexography, corrugated fibreboard	17
Screen printing	23'

on page 65, Criterion 9:

for: **'Criterion 9 — Information on the product**

The following information shall appear on the product:

"Please collect used paper for recycling".

Assessment and verification: the applicant shall provide a sample of the product packaging bearing the information required.',

read: **'Criterion 9 — Information on the product**

The following information shall appear on the product:

"Please collect used paper for recycling".

Assessment and verification: the applicant shall provide a sample of the product bearing the information required.'.

NOTICE TO READERS

Council Regulation (EU) No 216/2013 of 7 March 2013 on the electronic publication of the *Official Journal of the European Union*

In accordance with Council Regulation (EU) No 216/2013 of 7 March 2013 on the electronic publication of the *Official Journal of the European Union* (OJ L 69, 13.3.2013, p. 1), as of 1 July 2013, only the electronic edition of the Official Journal shall be considered authentic and shall have legal effect.

Where it is not possible to publish the electronic edition of the Official Journal due to unforeseen and exceptional circumstances, the printed edition shall be authentic and shall have legal effect in accordance with the terms and conditions set out in Article 3 of Regulation (EU) No 216/2013.

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